UROSURGE

January 24, 2000

Don St. Pierre
DRAERD
HFZ 470
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: UroSurge Percutaneous SANS device
Via Fax – (301) 594-2339

Dear Don:

Based on our conversation this morning, I am requesting that the PMA application for the UroSurge Percutaneous SANS device be converted, as discussed, for immediate FDA clearance through the Agency expanded "de novo" process (from Section 513 (f) (2) of the Federal Food, Drug, and Cosmetic Act - Evaluation of Automatic Class III Designation provision (FDAMA)).

Please contact me with any further information.

Sincerely,

Steven J. Preiss
Vice President,
Clinical and Regulatory Affairs

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